

## DENTINAL DESENSITIZING COMPOSITIONS

### BACKGROUND OF THE INVENTION

Hypersensitive teeth can cause pain and discomfort when subjected to changes in temperature, pressure, or chemical action. Exposure of the dentin frequently leads to hypersensitivity. Dentin exposure may occur due to recession of the gums, periodontal disease and improper dental care. The usual method of treating hypersensitive teeth employs a desensitizing dentifrice or solution. Some of the active ingredients used in desensitizing dentifrices include strontium chloride, strontium acetate, potassium nitrate, and potassium chloride, other treatments are applied professionally as a solution. These include solutions of ferric oxalate or potassium oxalate.

One approach to desensitization is to occlude exposed dentinal tubules. Dentinal tubules lead from the pulp to the surface of the dentin. When the surface of the tooth is eroded, the dentinal tubules become exposed to the external environment. The exposed dentinal tubules provide a pathway for transmission of fluid flow to the pulpal nerves and this is induced by changes in temperature, pressure and ionic gradients. By blocking the tubules, the external stimuli have a diminished effect, and less pain will be felt.

Some active ingredients, such as ferric oxalate, are known to form mineral deposits on the surfaces of exposed dentinal tubules, effectively blocking the openings. In some cases, the abrasive action from brushing may cause a smear layer to form over the surface of the tooth and thus plug up the open tubules. The accumulation of particulate matter from the interstitial fluid passing through the dentinal tubules or remineralization within the tubules can cause a natural occlusion of the tubules.

Nerve inactivation is another mechanism whereby desensitization can occur. This relies on the action of an active ingredient such as potassium nitrate on the nerves. By altering the ionic balance in the nerve, the threshold of nerve stimulation is increased. Thus a higher level of stimulation is needed to evoke a painful response.

The materials which have been used as active ingredients in the treatment of hypersensitive teeth are generally inorganic salts or hydrophobic compounds. Although hydrophilic polymers have been used in oral compositions as excipients or the like, they have not been suggested as being useful active ingredients for desensitization purposes. Most of the hydrophilic polymers have been used to control the viscosity of the oral formulation or to give it thixotropic properties.

An example of such a polymer is polyacrylic acid which is used as a thickener in dentifrice formulations. It has also been used in gels, mouthwashes and buccal adhesive patches. However, polyacrylic acid has also been used for other purposes. For example, Leonard et al. (U.S. Pat. No. 5,011,830) state an oral composition containing an alkali pyrophosphate salt, a fluoride salt and a polyacrylic acid or a copolymer of acrylic acid and another monomer can provide enhanced anti-calculus benefits. Gaffar (U.S. Pat. No. 3,956,480) uses an anionic polymer such as polyacrylic acid with chlorhexidine as an anti-calculus agent. Benedict and Sunberg (U.S. Pat. No. 4,661,341) describe the use of poly-

acrylic acid or copolymers of polyacrylic acid as anti-calculus agents.

Another polymer which is used in oral compositions is the copolymer of methyl vinyl ether and maleic anhydride (MVE/MA) or the hydrolyzed acid copolymer. The MVE/MA copolymer and its salts have been used to enhance anti-calculus, anti-plaque, and anti-caries activity, and to control mouth odor. It has also been used to stabilize active agents in dentifrice formulations.

Suhonen (U.S. Pat. Nos. 4,960,586; 4,961,924) uses the MVE/MA copolymer to stabilize stannous fluoride dentifrice compositions.

Gaffar et al. (U.S. Pat. No. 4,138,477) use a zinc compound with the MVE/MA copolymer in a composition to control mouth odor and also to prevent calculus, caries, plaque, and periodontal disease.

Wietfeldt (U.S. Pat. No. 4,965,067) uses the MVE/MA copolymer, a soluble fluoride ion source, and a strontium ion source in a dentifrice composition. The polymer is said to stabilize the combination of strontium and fluoride in the composition which will form a precipitate without stabilization.

Friedman (EP 0381445) claims an oral composition with an anti-hypersensitivity agent such as strontium chloride in a hydrophobic polymer which can be applied to the teeth. The polymer matrix has an affinity for the teeth and acts as a matrix for the sustained release of the active ingredient. An example of a carrier used is ethyl cellulose with polyethylene glycol as a plasticizer.

Mason (U.S. Pat. No. 4,992,258) discloses the use of montmorillonite clay and a MVE/MA copolymer in a dentifrice formulation for the treatment of hypersensitive teeth. It is asserted in this patent that the MVE/MA copolymer increases the effectiveness of the montmorillonite clay.

In none of the examples above or elsewhere, as far as we are aware, are these polymers claimed to provide adensitizing effect. Even in the Mason patent where a MVE/MA copolymer was used to increase the effectiveness of a desensitizing agent there is no attribution of such properties to the polymer.

Zinner et al., A New Desensitizing Dentifrice: Preliminary Report, JADA, Vol. 95 pp. 982-985, November 1977 reports that a Pluronic F127 based dentifrice, with or without sodium citrate, had some desensitizing efficacy. Pluronic F127 is a non-ionic water soluble copolymer of ethylene oxide and propylene oxide.

It has now been determined that water soluble or water swellable polyelectrolytes, i.e. polymers with functional groups that are capable of bearing one or more charged groups in an aqueous solution have desensitizing properties.

It is accordingly the object of this invention to provide new dentinal desensitizing agents. This and other objects of the invention will become apparent to those skilled in this art from the following detailed description.

### SUMMARY OF THE INVENTION

This invention relates to an oral composition and method which is useful for relieving pain and discomfort caused by hypersensitive teeth. More particularly, the invention relates to the use of a water soluble or water swellable polyelectrolyte or the partial salts thereof as a dental desensitization agent. The cations used to make the salt can include ammonium, alkylammonium, calcium, sodium, potassium, strontium, magnesium, zinc, aluminum, tin, iron, barium, lanthanum,